

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/801,518	03/16/2004	Donald J. Pinto	PH 7466 NP	3204	
23914 7	590 02/09/2006		EXAMINER		
LOUIS J. WILLE			FREISTEIN, ANDREW B		
BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT		•	ART UNIT	PAPER NUMBER	
P O BOX 4000		1626			
PRINCETON, NJ 08543-4000			DATE MAILED: 02/09/200	DATE MAILED: 02/09/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	· · · · · · · · · · · · · · · · · · ·					
	Application No.	Applicant(s)				
	10/801,518	PINTO ET AL.				
Office Action Summary	Examiner	Art Unit				
	Andrew B. Freistein	1626				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
_	ocombor 2005					
,	· · · · · · · · · · · · · · · · · · ·					
, -						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
 4) Claim(s) 1-21 is/are pending in the application 4a) Of the above claim(s) 18-21 is/are withdrav 5) Claim(s) is/are allowed. 6) Claim(s) 1-7 and 9-14 is/are rejected. 7) Claim(s) 1-17 is/are objected to. 8) Claim(s) are subject to restriction and/o 	vn from consideration.	·				
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the I drawing(s) be held in abeyance. See tion is required if the drawing(s) is objected.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Burea * See the attached detailed Office action for a list	es have been received. Es have been received in Application rity documents have been received u (PCT Rule 17.2(a)).	on No ed in this National Stage				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F	r (PTO-413) ate Patent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/04/2004. 5) Notice of informal Patent Application (PTO-						

DETAILED ACTION

Claims 1-21 are currently pending in the instant application.

Priority

This application claims benefit from US Provisional Application No. 60/455,709, filed 03/18/2003.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on 10/04/2004 and 05/26/2004, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

Applicant's election of Group I, claims 1-8 and 17-21, and the species

, in the reply filed on 12/08/2005 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Application/Control Number: 10/801,518

Art Unit: 1626

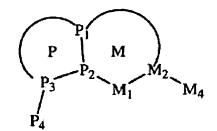
Claims 1-7 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a compound of the formula (I), P_4 -P-M-M₄, wherein M is a 3-10-membered carbocycle or a 4-10-membered heterocycle consisting of: carbon atoms and 1-3 heteroatoms selected from O, $S(O)_p$, N, and NZ^2 .

The definitions of P₄, P, M and M₄, are so broad that they are indefinite, unsearchable, and unclassifiable. There is no clear unambiguous claim to indicate how the variables are bonded to each other and what rings are in each compound.

According to the STN search report, there are over 750,000 projected answers for this core structure and no proper search can be performed (see STN International, Columbus, OH, search performed 01/10/2006).

Similarly, claim 2-7 and 9-14 are indefinite for the same reasons as claim 1. For



example, claim 2 is drawn to a formula

, wherein ring M,

including P₁, P₂, M₁ and M₂ is a 5, 6, or 7 membered carbocycle or a 5, 6, or 7 membered heterocycle. Claim 3 is drawn to 105 different structures for variable M and 44 different structures for variable P. Thus all of claims 1-7 and 9-15 contain widely divergent variables, which creates unsearchable claims.

Art Unit: 1626

The claims are unclassifiable, because the variables P₄, P, M and M₄, do not indicate a specific ring. For example, compounds containing six-membered hetero rings having two or more heteroatoms of which at least one is N is classified in class 544; compounds containing six-membered hetero rings consisting of one N and five carbon atoms is classified in class 544; and five-membered hetero rings having at least one N atom are classified in class 548. Since the definitions of the variables P₄, P, M and M₄ define rings of 3-10 members with 0-3 heteroatoms, no proper classification of the compounds of the instant application can be made.

Further, since no proper classification can be made, no prior art search of the class and subclass of claims 1-7 and 9-15 can be made. Therefore, the claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See MPEP 903.07 and 904 (classification and search).

Status of the Claims

Claims 1-17 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:

Application/Control Number: 10/801,518 Page 5

Art Unit: 1626

R¹⁸
$$\mathbb{R}^{48}$$
 \mathbb{R}^{48} \mathbb{R}^{48} \mathbb{R}^{48} , wherein:

Q¹ is as defined in claim 1;

Q² is as defined in claim 1;

Q is as defined in claim 1;

R is as defined in claim 1;

R^{1a} is as defined in claim 1; and

R^{4a} is as defined in claim 1.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:

Art Unit: 1626

All compounds of the Formula (I), P₄-P-M-M₄, that are not provided above <u>and</u> more specifically, compounds of the formula

B¹ and B² are as defined in claim 1.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiazolidine, piperazine, quinoline, thiophene, morpholine, oxazol, pyran, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

Application/Control Number: 10/801,518 Page 7

Art Unit: 1626

Double Patenting

The Inventors of the instant application have many patents and copending applications with a similar core structure. However, Examiner finds no Double Patenting issues with respect to the scope of the elected invention as defined above.

The closest relevant art with respect to double patenting is US Pat. No. 6,750,225. This patent differs from the instant application because the instant

$$\mathbb{R}^{4a}$$
 \mathbb{Q}^2 \mathbb{Q}^2

application claims the variable "B" to represent:

, which is a heterocycle

with at least one N atom and one double bond in the ring. However, US Pat. No.

6,750,225 claims a compound with pyridine or imidazole, which are Nitrogen-containing heterocycles with two and three double bonds respectively. Thus, the patent claims different compounds.

Closest Relevant Art

The closest relevant art is Fevig et al. (WO 00/39131), which would be considered prior art under 35 USC 102(b) of <u>non-elected</u> subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1626

Claims 1-3 of the instant application are drawn to a compound of formula I, P₄-P-

M-M₄, wherein M is

; M_4 is Z-A-B; Z is a bond; A is C_6 -carbocycle,

substituted with 0-2 R4; R4 is F; B is

Q¹ and Q² are each N; Q is a 5-

membered heterocycle; R⁴a is C₁alkyl or (CR³R³a),NR²R²a; R³ and R³a are H; r is 1; and

R² and R^{2a} are each C₁alkyl; P is

; R^{1a} is $(CR^3R^{3a})_{r}$ - R^{1b} ; r is 0; R^{1b} is

 $(CF_2)_rCF_3$; r is 0; P₄ is G₁-G; G₁ is absent; G is Formula IIa,

phenyl; D is a six-membered heterocyclic ring consisting of carbon atoms, and 0-2 heteroatoms selected from N and O, which is substituted with R; and R is NH₂.

Claim 17 is drawn to a pharmaceutical composition comprising a therapeutically effective amount of a compound of Formula (I) and a pharmaceutically acceptable carrier.

Application/Control Number: 10/801,518

Art Unit: 1626

Page 9

Fevig et al. disclose the compounds:

(see Fevig, et al, STN International

(2006) HCAPLUS Database, Columbus, OH, Accession No. 2000:457072, Reg. Nos. 280119-13-3 and 280119-14-4).

Fevig et al. disclose pharmaceutical compositions comprising the compounds disclosed (see US 6,413,980, col. 216, line 54 – col. 220, line 22).

Claim Objections

Claims 1-17 are objected to as containing non-elected subject matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Application/Control Number: 10/801,518

Art Unit: 1626

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein Patent Examiner, AU 1626 Soseph K. McKane

Supervisory Patent Examiner, AU 1626

Page 10

Date: February 3, 2006